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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,970	10/16/2003	Rudolf Pachl	5727-73662	8089
49437 7590 12/03/2007 BARNES & THORNBURG LLP (Roche) 11 SOUTH MERIDAN STREET INDIANAPOLIS, IN 46204			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/686,970

Applicant(s)

PACHL ET AL.

Examiner

Lore Ramillano

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-31 is/are allowed.
- 6) ☒ Claim(s) 19,21,22 and 32-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/16/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of Claims*

1. In applicant's reply filed on 9/20/07, applicant amended claim 32. Claims 19 and 21-38 are pending and under examination.

### *Response to Amendment*

### *Allowable Subject Matter*

2. Claims 23-31 are allowed. The reasons for allowance are stated in the prior Office action (filed on 6/4/07).

### *Prior art rejections*

3. The rejection over Moorman in view of Polito is withdrawn. A new rejection follows. The rejection over Moorman; Fleming; Moorman in view of Carr; Moorman in view of Caspers; Moorman in view of Mach; and Moorman in view of Mach, and further in view of applicant's admitted prior art are maintained.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 21, 32, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Moorman (US 5356782).

Moorman teaches a method comprising: a test field (10); a reagent in the test field (i.e. regions I, II, and III), wherein (i) the interaction between the reagent and the analyte causes a first photometrically detectable signal and (ii) the first photometrically detectable signal is a function of concentration of the analyte in the sample (i.e. column 8, lines 31-43); and a control substance in the test field, wherein (i) the interaction between the control substance and the sample matrix causes a second photometrically detectable signal and (ii) the second photometrically detectable signal is a function of the amount of the sample applied to the test field (i.e. column 8, lines 3-30). Moorman's signals are photometrically detectable because he teaches in column 17, lines 57-62, for example, that the interactions disclosed above were observed by fluorescence under long wave UV light.

Furthermore, Moorman teaches that the latter interaction stated above is a function of the amount of sample applied to the test field because he teaches in column 14, lines 47 to column 15, line 14, for example, that the test strips can be prepared to perform "concentration assay," which is an assay to determine whether an analyte of interest is present in excess of insufficiency in a sample.

6. **Claims 32, 33, and 35** are rejected under 35 U.S.C. 102(b) as being anticipated by Fleming et al. ("Fleming," US 6365417).

In figures 1-7, Fleming teaches a method comprising: a test field (i.e. 80 and 86); a reagent (i.e. capture agents) in the test field, wherein (i) the interaction between the reagent and the analyte causes a first photometrically detectable signal and (ii) the first photometrically detectable signal is a function of concentration of the analyte in the sample; and a control substance (i.e. fluorescein, 102, column 7, lines 7-8) in the test field, wherein (i) the interaction

between the control substance and the sample matrix (i.e. saliva or other oral secretions collected) causes a second photometrically detectable signal and (ii) the second photometrically detectable signal is a function of the amount of the sample applied to the test field (i.e. column 6, line 64 to column 7, line 8; column 9, line 35 to column 10, line 10). Fleming's signals are photometrically detectable because he teaches in column 6, line 64 to column 7, line 8, for example, that the interactions disclosed above were observed by visual, spectroscopic, photochemical, biochemical, immunochemical, electrical, optical or chemical means.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. **Claims 19, 22, and 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Yamamoto (US 4666578).

The teachings of Moorman are stated above. Moorman does not specifically teach correcting the analyte content of the sample if the amount of the sample placed on the test element is determined to be less than a predetermined calibration value.

Yamamoto teaches that when samples are applied onto the substrate by means of the applicator having a number of applying tips, amounts of samples applied on the substrate are slightly varied from each other. Further the degree of dyeing is varied in accordance with the positions of samples in the dyeing vessel. In the present embodiment, in order to remove the above mentioned variations, there are introduced second correction coefficients  $K_{sub.1}$ ,  $K_{sub.2}$  . . .  $K_{sub.N}$  for compensating the variation in amount of applied samples on the substrate. (i.e. column 5, lines 1-30). It would have been obvious to a person of ordinary skill in the art to

modify Moorman's invention by incorporating Yamamoto's correction step because it would be cost- and time- efficient to have a means for correcting the amount of sample applied to the test element, which fall below a certain threshold, since it would prevent the user from having to perform the entire procedure again.

9. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Carr et al. ("Carr," WO 01/25171 A1).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising a chromophore. Carr teaches utilizing a chromophore because it enables quantitation of the products of a synthesis to be carried out. Carr further teaches that such quantitation can be absolute quantitation or relative quantitation, or both. (i.e. p. 7, lines 23-30). It would have been obvious to a person of ordinary skill in the art to incorporate a chromophore into Moorman's invention because a chromophore has a very strong absorption at a unique or characteristic wavelength, which is usually distinct from the wavelengths at which the maximum absorbances of a typical substrate molecule might be found. (i.e. p. 7, lines 23-30).

10. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Caspers et al. ("Caspers," US 4081672).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising a fluorescein. Caspers teaches utilizing sodium fluorescein dye because it has the advantage that fluorescence may be detected in solution concentrations as small as  $1 \times 10^{-7}$  mole concentrations where at about 5200Å the extinction coefficient is roughly  $0.01 \text{ cm}^{-1}$ . (i.e. column 3, lines 9-15). It would have been obvious to a

person of ordinary skill in the art to modify Moorman by incorporating a fluorescein dye as a control substance since the amount of analyte that is collected in each sample is in minute amounts and incorporating a fluorescein dye would enable that analyte to be detectable.

11. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Mach et al. ("Mach," US 5723308).

The teachings of Moorman are stated above. Moorman does not specifically teach having a control substance comprising chlorophenol red. Mach teaches the benefit of using a large excess of chlorophenol red is the bright red color of chlorophenol red in contrast with the other colors in a solution allows easier and faster detection of the specimen (i.e. column 5, lines 38-50). It would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating chlorophenol red as the control substance because it would be desirable to use a control substance that produces a distinguishable color when it interacts with the sample to make it easier for the analyst to quickly determine the signal produced by the control substance.

12. **Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman in view of Mach, as applied to claim 36 above, and further in view of applicant's admitted prior art on page 15 of the specification.

The teachings of Moorman and Mach are stated above. Moorman in view of Mach does not specifically teach having a reagent comprising phosphomolybdic acid. However, applicant teaches that the use of 2, 18 phosphomolybdic acid in the detection of glucose is known in the art. It would have been obvious to a person of ordinary skill in the art to modify the modified Moorman by incorporating phosphomolybdic acid as a reagent for glucose because it would be

desirable to utilize a reagent that is easily available and well-known to be used for such detection.

***Response to Arguments***

13. Applicant's arguments filed 9/20/07, with respect to claims 19, 21, 22 and 32-37 have been fully considered but they are not persuasive.

**35 USC 102(b) rejection by Moorman**

In response to applicant's argument, with regard to claim 21, that Moorman fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., reagents for detecting the total amount (i.e. volume) of the sample applied to the test field; and two separate reactive agents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, claim 21 recites that the reagent and the analyte in the sample determine the analyte content, which can be broadly interpreted to mean, for example, detecting an analyte. Furthermore, claim 21 recites a singular reagent and not a plurality of reagents.

In response to applicant's argument, with regard to claims 32 and 33, that Moorman fails to provide any reagents for detecting the total amount (i.e. volume) of the sample applied to the test field, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, because Moorman discloses a reagent and structural



limitations recited in claims 32 and 33, Moorman properly reads on the functional language recited in claims 32 and 33.

In response to applicant's argument, with regard to claims 32 and 33, that Moorman fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., two separate reactive agents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, claims 32 and 33 recite a singular reagent and not a plurality of reagents.

35 USC 102(b) rejection by Fleming

In response to applicant's argument that Fleming's "sufficiency indicator" does not interact with the sample matrix to cause a second photometrically detectable signal to be produced when the test field is illuminated with light, examiner disagrees. The control substance (i.e. fluorescein, 102, column 7, lines 7-8) in the test field is capable of interacting with a sample matrix (i.e. saliva or other oral secretions collected) to cause a photometric signal because the labels (i.e. fluorescein) utilized by Fleming are capable of producing a signal observed by visual, spectroscopic, photochemical, biochemical, immunochemical, electrical, optical or chemical means (i.e. column 6, line 64 to column 7, line 8).

In response to applicant's argument, with regard to claims 32 and 33, that Fleming fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., adjusting the detected analyte levels when the device is underdosed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations

from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Fleming fails to disclose two separate reactive agents: 1) a control substance and 2) a reagent, examiner disagrees. Fleming discloses a reagent (i.e. capture agents in column 4, lines 49-59, column 8, lines 53-65) and a control substance (i.e. fluorescein, column 7, lines 7-8).

In response to applicant's argument, with regard to claims 32 and 33, that Fleming fails to disclose that the control substance interacts with the sample matrix to produce a signal proportional to the volume of sample, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, because Fleming discloses the structural limitations recited in claims 32 and 33, Moorman properly reads on the functional language recited in claims 32 and 33.

35 USC 103(a) rejection over Moorman in view of Carr

In response to applicant's argument that Carr is devoid of any suggestion that a chromophore could be used to quantitate the total amount of liquid that is placed on a test element, examiner does not find this argument convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Moorman, as stated above, reads on the structural limitations recited in claim 32. Carr discloses a chromophore. The combination of Moorman

and Carr is proper because it would have been obvious to a person of ordinary skill in the art to incorporate a chromophore into Moorman's invention because a chromophore has a very strong absorption at a unique or characteristic wavelength, which is usually distinct from the wavelengths at which the maximum absorbances of a typical substrate molecule might be found. (Carr, i.e. p. 7, lines 23-30). Because examiner has provided sufficient motivation to combine the references, the rejection is proper.

35 USC 103(a) rejection over Moorman in view of Caspers

In response to applicant's argument that Caspers's fluorescein dye solution fails to suggest that it could be used as a control substance to determine the amount of sample that is placed in contact with the control substance, examiner does not find this argument convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Moorman, as stated above, reads on the structural limitations recited in claim 32. Casper discloses a sodium fluorescein dye. The combination of Moorman and Casper is proper because it would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating a fluorescein dye as a control substance since the amount of analyte that is collected in each sample is in minute amounts and incorporating a fluorescein dye would enable that analyte to be detectable. Because examiner has provided sufficient motivation to combine the references, the rejection is proper.

35 USC 103(a) rejection over Moorman in view of Mach

In response to applicant's argument that Mach's is devoid of any suggestion that phosphomolybdic acid could be used to quantitate the amount (volume) of liquid that is placed on a test element, examiner does not find this argument convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, Moorman, as stated above, reads on the structural limitations recited in claim 32. Casper discloses that the benefit of using a large excess of chlorophenol red is the bright red color of chlorophenol red in contrast with the other colors in a solution because it allows easier and faster detection of the specimen. The combination of Moorman and Mach is proper because it would have been obvious to a person of ordinary skill in the art to modify Moorman by incorporating chlorophenol red as the control substance because it would be desirable to use a control substance that produces a distinguishable color when it interacts with the sample to make it easier for the analyst to quickly determine the signal produced by the control substance. Because examiner has provided sufficient motivation to combine the references, the rejection is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

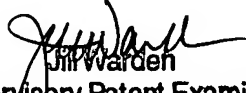
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Lore Ramillano  
Examiner  
Art Unit 1797

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700